



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/045,903	01/11/2002	David Michael Goldstein	R0038G-DIV	4961

24372 7590 10/25/2002

ROCHE BIOSCIENCE
3401 HILLVIEW AVENUE
INTELLECTUAL PROPERTY LAW DEPT., MS A2-250
PALO ALTO, CA 94304-9819

EXAMINER

STOCKTON, LAURA LYNNE

ART UNIT PAPER NUMBER

1626

DATE MAILED: 10/25/2002

6

Please find below and/or attached an Office communication concerning this application or proceeding.



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
--------------------	-------------	-----------------------	------------------

EXAMINER

ART UNIT	PAPER NUMBER
----------	--------------

6

DATE MAILED:

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☒ Responsive to communication(s) filed on August 22, 2002

☒ This action is FINAL.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), ~~which~~ whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

- ☒ Claim(s) 2-16, 22-31 and 33-35 are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
- ☐ Claim(s) _____ is/are allowed.
- ☒ Claim(s) 2-7, 12, 16, 22-24, and 33-35 are rejected.
- ☒ Claim(s) 8-11, 13-15, and 25-31 are objected to.
- ☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) _____.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

- ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- ☐ Notice of Reference Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

--SEE OFFICE ACTION ON THE FOLLOWING PAGES--

10/045,903
* U.S. GPO: 1996-404-496/40517

DETAILED ACTION

Claims 2-16, 22-31 and 33-35 are pending in the application.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 2-6, 16, 22-24 and 33-35 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 19-21 of U.S. Patent No. 6,376,527. Although

the conflicting claims are not identical, they are not patentably distinct from each other because the instant claims and the claims in the patent differ only by generic description of the pyrazole product used in the method.

See, for example, the patent's claim 19 wherein R^1 is hydrogen, R^2 is hydrogen, A and B are each aryl, R^3 is heteroalkoxy, R^4 , R^5 and R^6 are each hydrogen. One skilled in the art would thus be motivated to prepare pyrazole products embraced by the patent to arrive at the pyrazole products found in the instant claims with the expectation that the obtained pyrazole products would be useful in treating inflammatory disorders such as arthritis. Therefore, the instant claimed method of using the pyrazole products would have been suggested to one skilled in the art.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 2-7, 12, 16, 22-24 and 33-35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Faraci et al. {WO 94/13643}. WO 94/13643 is in the same patent family as U.S. Pat. 5,712,303 which is listed on the 1449 Form.

Determination of the scope and content of the prior art (MPEP §2141.01)

Applicants claim a method of treating a disease in a mammal treatable by administration of a p38 MAP kinase inhibitor (such as inflammation disorders) by administering pyrazole products. Faraci et al. teach pharmaceutically active pyrazole products that are structurally similar to the pyrazole products that are administered in the instant claimed method. See in Faraci et al. (pages 1 and 2), for example, wherein A is $-\text{C}(=\text{O})$, R_1 is amino, R_2 is alkyl, R_3 is phenyl substituted

with hydroxy-alkyl and R_4 is phenyl. Also see, for example, the products on page 31, lines 5 and 12; page 39, line 11; and page 44, lines 12-14.

Faraci et al. teach the pyrazole products are useful in treating disorders such as inflammatory disorders and immune suppression (page 5, lines 1-12).

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the teaching in the prior art and the invention instantly claimed is that of generic description of the pyrazole products being administered for the intended use.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The motivation to make the pyrazole products derives from the expectation that structurally similar compounds would possess similar activity (e.g. an anti-inflammatory). One skilled in the art would thus be motivated to prepare pyrazole products embraced by Faraci et al. to arrive at the pyrazole products found in the instant claims with the expectation that the obtained pyrazole products would be useful in

treating inflammatory disorders such as arthritis. Therefore, the instant claimed method of using the pyrazole products would have been suggested to one skilled in the art.

Response to Arguments

Applicants' arguments filed August 22, 2002 have been fully considered. In regard to the obviousness-type double patenting rejection, Applicants state that a terminal disclaimer will be filed after all other outstanding issues have been resolved.

Applicants argue that the substituents represented by the instant R^3 variable do not overlap with the substituents that can be substituted on the phenyl ring (R^3 variable) in Faraci et al.

In response, Faraci et al. do teach substituents which overlap with the substituents represented by the instant R^3 variable. See, for example, the instant (c) and (o) definitions in R^3 in claim 1 and the products on page 36, line 10; page 40, line 15; page 43, line 19; and page 44, lines 12-14 of Faraci et al. Therefore, the rejection is maintained.

Allowable Subject Matter

Claims 8-11, 13-15 and 25-31 are objected to as being dependent upon a rejected base claim, but would be allowable over the art of record if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

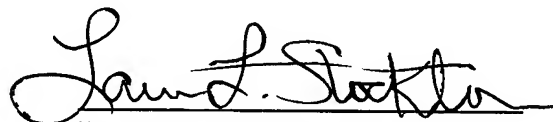
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the

statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Laura L. Stockton whose telephone number is (703) 308-1875. The examiner can normally be reached on Monday-Friday from 6:00 am to 2:30 pm. If the examiner is out of the Office, the examiner's supervisor, Joseph McKane, can be reached on (703) 308-4537.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-1235.

The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

A handwritten signature in black ink, appearing to read "Laura L. Stockton", written over a horizontal line.

Laura L. Stockton, Ph.D.
Patent Examiner
Art Unit 1626, Group 1620
Technology Center 1600

October 24, 2002